

Use of Food Allergy Panels by Pediatric Care Providers Compared With Allergists

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abstract

BACKGROUND AND OBJECTIVE: Immunoglobulin E (IgE)-mediated food allergies affect 5% to 8% of children. Serum IgE levels assist in diagnosing food allergies but have low positive predictive value. This can lead to misinterpretation, overdiagnosis, and unnecessary dietary elimination. Use of IgE food allergen panels has been associated with increased cost and burden. The scale of use of these panels has not been reported in the medical literature.

METHODS: We conducted a retrospective review of a commercial laboratory database associated with a tertiary care pediatric academic medical center for food IgE tests ordered by all provider types during 2013.

RESULTS: A total of 10 794 single-food IgE tests and 3065 allergen panels were ordered. Allergists ordered the majority of single-food IgE tests (58.2%) whereas 78.8% of food allergen panels were ordered by primary care providers (PCPs) ($P < .001$). Of all IgE tests ordered by PCPs, 45.1% were panels compared with 1.2% of orders placed by allergists ($P < .001$). PCPs in practice for >15 years ordered a higher number of food allergen panels ($P < .05$) compared with PCPs with less experience. Compared with allergists, PCPs ordered more tests for unlikely causes of food allergies ($P < .001$). Total cost of IgE testing and cost per patient were higher for PCPs compared with allergists.

CONCLUSIONS: Review of food allergen IgE testing through a high volume outpatient laboratory revealed PCPs order significantly more food allergen panels, tests for uncommon causes of food allergy, and generate higher cost per patient compared with allergists. These results suggest a need for increased education of PCPs regarding proper use of food IgE tests.



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WHAT'S KNOWN ON THIS SUBJECT: Indiscriminate use of food immunoglobulin E (IgE) testing without consideration of clinical history is discouraged by guidelines because of poor positive predictive values. Commercial laboratories offer panels containing several foods, which are subject to misinterpretation and overdiagnosis.

WHAT THIS STUDY ADDS: This study identifies greater use of IgE panels by primary care pediatricians compared with allergists. Physicians with longer duration of practice order more IgE panels. The use of specific IgE panels is associated with higher cost per patient.

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Food allergies affect ~5% to 8% of children, with increasing prevalence during the past 2 decades.^{1,2} There are a variety of immune-mediated food hypersensitivity disorders, but only immunoglobulin E (IgE)-mediated food allergy presents with immediate-onset and reproducible reactions that can cause a range of symptoms, including anaphylaxis and, in rare cases, death.³ Accurate diagnosis of IgE-mediated food allergy is critical for effective self-management, which entails strict avoidance of the offending food in addition to immediate access to self-injectable epinephrine for patients with a history of systemic reactions, in case of accidental exposure.^{4,5}

Oral food challenges are considered the gold standard to confirm a diagnosis of IgE-mediated food allergy.⁶ However, this is not always feasible or warranted, particularly when there is risk of anaphylaxis. Other widely available methods to assist in the diagnosis of IgE-mediated food allergy include percutaneous skin prick testing and laboratory assays to measure levels of serum food-specific IgE (sIgE).^{7,8} Many commercial laboratories offer panels containing multiple inhalant and/or food sIgE levels, touting convenience and cost effectiveness.

Current clinical guidelines strongly discourage indiscriminate use of skin prick and food sIgE testing, which are both associated with poor sensitivity and high rates of falsely elevated and clinically insignificant results.^{6,9} Many more children will be sensitized to foods than will experience allergic reactions on exposure.¹⁰ Interpretation of food sIgE results without consideration of the clinical history can lead to overdiagnosis of food allergy, increased cost of evaluation, unnecessary dietary elimination, and the potential for adverse consequences for the patient and their family, including decreased quality of life and potential nutritional deficiencies.^{10–12} To our

knowledge, there are no published studies that have quantified the use of sIgE panels by clinicians. The aim of our study was to characterize and quantify the use of food sIgE panels by primary care providers (PCPs) and allergists.

METHODS

We conducted a retrospective review of the electronic database of a high-volume outpatient laboratory in the Department of Pathology and Laboratory Medicine at Nationwide Children's Hospital (NCH; Columbus, OH) for all food sIgE tests ordered between January 1, 2013 and December 31, 2013. The NCH laboratory has a large referral base throughout the state of Ohio and processed 2 637 438 billable laboratory tests in 2013. Data were analyzed for number and type of individual food sIgEs and all panels containing at least 1 food allergen. Laboratory testing for single sIgE toward aeroallergens, medications, hymenoptera, and latex were excluded from analysis.

Serum IgE testing was performed by using ImmunoCAP Allergen specific assays on the Phadia Immunoassay Analyzer (ThermoScientific, Portage, MI) in the NCH laboratory for both aeroallergens and food allergens, with some select testing sent to outside reference laboratories. Serum IgE testing can be ordered for individual allergens, or several different allergen panels, within which multiple sIgE tests are bundled together. In 2013, the NCH laboratory offered 6 allergen panels that contained at least 1 food (Supplemental Information). Orders to the laboratory can be placed from within the NCH system of providers, as well as from clinicians in the surrounding community.

For the purposes of this study, ordering clinicians (physicians, nurse practitioners [NPs], and physician assistants [PAs]) were classified

according to their primary area of clinical expertise and divided into categories, including: allergy and immunology (A/I), PCP (including pediatricians, family medicine, and internal medicine), and gastroenterology (GI). All remaining subspecialties were labeled and grouped as "other" because of the relatively small number of tests ordered and providers. The time since completion of residency or specialty fellowship training was determined for each clinician through review of their licensure, medical staff privileges, or both. Clinician data were extracted to a database (Microsoft Excel, 2010) for analysis and de-identified. Categorical variables from within each group and between 2 groups were analyzed by χ^2 . Continuous variables were compared with the Mann-Whitney test. Mean values among multiple groups were compared by using one-way analysis of variance. For statistical comparisons, $P < .05$ was considered statistically significant. Because no patient-identifying information was included in any data collection, the institutional review board at NCH deemed this study exempt from formal review.

RESULTS

During our 1-year study time period, 10 794 single-food sIgE tests and 3065 allergen panels containing at least 1 food sIgE were ordered by 447 individual clinicians, encompassing 16 medical and surgical specialties (Table 1). Among PCPs, 247 (88.8%) of physicians were pediatricians and the remaining physicians were identified as either family practice ($n = 28$, 10.2%) or internal medicine ($n = 3$, 1.1%). Family practice and internal medicine physicians ordered only 2.4% of all sIgE tests among PCPs. Pediatricians ordered the most single-food sIgEs among PCPs, comprising 97.9% of the single-food sIgE tests ordered by PCPs ($P < .001$).

Overall, allergists ordered the majority of single-food sIgE tests (58.2%), compared with 23.1% obtained by PCPs ($P < .001$). Of 7059 single-food sIgEs ordered by subspecialist physicians, A/I ordered 88.9%, GI ordered 9.2%, and the remaining subspecialties accounted for 1.8% ($P < .001$; Table 1). Among the 3065 allergen panels containing foods that were ordered, 78.8% were obtained by PCPs ($P < .001$), with 14.4% ordered by GI and 4.1% ordered by A/I. The combined remaining subspecialists accounted for <3% of allergen panel orders (Table 1).

NPs and PAs from primary care ($n = 47$), allergy ($n = 5$), and other specialties ($n = 11$) ordered 1660 food-containing sIgE tests during our study period, which accounted for 12% of all orders (Table 1). The percentage of panels containing food allergens ordered was similar between PCPs and primary care NP/PAs (45.1% vs 41.4%; $P = .05$). Within A/I, NP/PAs ordered food allergen sIgE panels more frequently than allergists (6.4% vs 1.2%; $P < .001$).

Allergists ordered significantly more total sIgE tests per physician compared with PCPs (mean, 154.98 ± 247.01 vs 16.35 ± 60.52) (Table 2). However, 45.1% of all sIgE tests ordered by PCPs were panels, compared with only 1.2% of orders placed by allergists. Overall, allergists ordered more sIgE tests per patient (7.11 ± 5.38 vs 2.33 ± 3.33; $P < .001$) compared with PCPs, but less panels (1.01 ± 0.11 vs 1.33 ± 0.77; $P < .001$). The mean age of patients being evaluated for food allergies was similar between both PCPs (5.92 ± 4.86 years; range, 1 month to 18 years) and A/I (5.99 ± 4.08 years; range 3 months to 18 years) (Table 2). During the study period, 73% ($n = 205$) of PCPs had been in practice for ≥10 years (mean, 16.42 ± 9.69 years; range, 0–45 years). The duration of practice among allergists was similar,

TABLE 1 Distribution of IgE Tests by Provider Type

Provider Type	No. of Providers	Total sIgE	Single sIgE	Panel sIgE
		No.	No. (%)	No. (%)
Physician				
Primary care ^a	278	4544	2497 (55)	2047 (45.1)
Allergy	41	6354	6277 (98.8)	77 (1.2)
GI	27	1092	652 (59.7)	440 (40.3)
Other specialist ^b	38	209	130 (62.2)	79 (37.8)
NP/PA				
Primary care	47	889	521 (58.6)	368 (41.4)
Allergy	5	732	685 (93.6)	47 (6.4)
Other ^c	11	39	32 (82.1)	7 (17.9)

^a Pediatrics ($n = 247$), family practice ($n = 28$), and internal medicine ($n = 3$).

^b Other physician: cardiology ($n = 4$), dentistry ($n = 1$), dermatology ($n = 2$), emergency medicine ($n = 4$), endocrinology ($n = 2$), neonatology ($n = 1$), obstetrics/gynecology ($n = 2$), otolaryngology ($n = 9$), critical care ($n = 1$), surgery ($n = 1$), hematology ($n = 1$), infectious disease ($n = 1$), pulmonary ($n = 9$).

^c Other NP/PA: dermatology ($n = 1$), emergency medicine ($n = 4$), neonatology ($n = 1$), GI ($n = 4$), orthopedics ($n = 1$).

TABLE 2 Differences in sIgE Orders Between PCPs and Allergists

	Primary Care	Allergy	<i>P</i>
Providers, No.	278	41	
Total sIgE, No.	4544	6354	
Mean per physician, No. (SD)	16.35 (60.52)	154.98 (247.01)	<.001
Mean per patient, No. (SD)	2.33 (3.33)	7.11 (5.38)	<.001
Patient mean age, y (SD)	5.92 (4.86)	5.99 (4.08)	.71
IgE panels, No. (%)	2047 (45.1)	77 (1.2)	
Mean per physician, No. (SD)	7.36 (15.76)	1.88 (4.27)	.002
Mean per patient, No. (SD)	1.33 (0.77)	1.01 (0.11)	<.001
Patient mean age, y (SD)	5.53 (4.83)	5.99 (4.03)	.41
Single IgE, No. (%)	2497 (55)	6277 (98.8)	
Mean per physician, no. (SD)	8.98 (48.19)	153.1 (246.56)	<.001
Mean per patient, no. (SD)	5.22 (5.43)	7.32 (5.41)	<.001
Patient mean age, y (SD)	6.25 (4.90)	5.99 (4.48)	.33

TABLE 3 Ordering Patterns of sIgE Tests According to Duration of Practice of PCPs

Years in Practice	0–9	10–15	≥16	<i>P</i>
Physicians, no. (%)	75 (27.0)	69 (24.8)	134 (48.2)	
Years of experience				
Mean, y (SD)	5.53 (2.60)	12.58 (1.70)	24.5 (7.14)	<.001
Median (IQR)	5 (4–8)	13 (11–14)	23 (19–29)	
Total sIgE tests, no.	765	535	3244	.111
Mean per physician, no. (SD)	10.2 (28.25)	7.75 (9.70)	24.21 (83.91)	
Median (IQR)	3 (1–10)	4 (1–10)	7 (3–16)	
sIgE panels, no.	391	315	1341	.025
Mean per physician, no. (SD)	5.21 (8.78)	4.57 (6.52)	10.01 (20.99)	
Median (IQR)	2 (1–6)	2 (1–5)	4.5 (2–10.75)	
Single sIgE, no.	374	220	1903	.216
Mean per physician, no. (SD)	4.99 (21.25)	3.19 (5.45)	14.20 (67.33)	
Median (IQR)	0 (0–3)	1 (0–4)	0 (0–6)	

IQR, interquartile range.

with 70.7% ($n = 29$) in practice for ≥10 years (mean = 18.1 ± 12.18; range, 1–46 years). Table 3 compares sIgE tests ordered by PCPs according to their duration of practice. PCPs in practice for ≤15 years ordered ~50% fewer sIgE panels compared with PCPs in practice for ≥16 years.

Regarding single-food sIgE, allergists were much more likely to order testing for one of the 8 most common food allergens (cow's milk, egg, wheat, soy, peanut, tree nuts, fish, and shellfish, which account for >90% of all IgE-mediated food allergies¹³) compared with PCPs

(78.3% of all single sIgE tests compared with 65.9%; $P < .001$). Compared with allergists, PCPs ordered significantly more sIgE tests for foods associated with a low prevalence of IgE-mediated food allergy, such as strawberry, beef, corn, and tomato (Fig 1).

The most frequently ordered food-containing allergen panel was the Food Allergy Profile (81.4%, $n = 2496$), which included 11 foods: clam, cod, corn, egg, milk, peanut, scallop, shrimp, soy, walnut, and wheat. The Food Allergy Profile was ordered most frequently by PCPs (75%), followed by GI (11%) and A/I (4%). The second most frequently ordered profile was the Childhood Allergy Profile (14.7%, $n = 450$), which included 6 food sIgEs (cod, milk, egg, peanut, soy, and wheat) combined with 5 inhalant allergen sIgEs (cat dander, cockroach, dog dander, dust mite, and alternaria) (Supplemental Information). This test was also most frequently ordered by PCPs (87%), with GI and pulmonary physicians ordering 2% and 4%, respectively. The Childhood Allergy Profile was infrequently ordered by A/I physicians, who accounted for <0.01% of the orders for this profile.

During the study time period, the average laboratory charge reported by the *CodeMap 2013 Medicare Reimbursement Manual for Laboratory and Pathology Services* for each individual sIgE was \$26.92. To generate the cost of each panel, the individual cost of each sIgE was multiplied by the number of allergens contained within the panel. The cost of each panel ranged from \$134.60 for the Seafood Allergy Profile containing 5 food allergens to \$619.16 for the Childhood/Respiratory Allergy Profile, which contains 23 food and inhalant allergens. The total cost of all sIgE tests ordered per patient was approximately twice as expensive for PCPs, (\$399.10 compared with

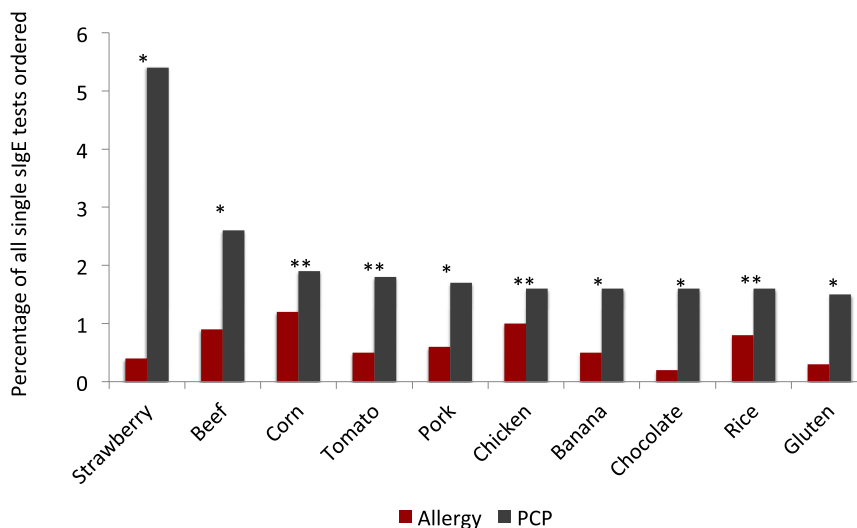


FIGURE 1 Uncommon causes of food allergy ordered as single sIgE by provider type. * $P < .001$; ** $P < .02$.

TABLE 4 Cost Differential for sIgE Testing Between PCPs and Allergists

	PCPs, n = 278	Allergists, n = 41
Single-food IgE		
Total cost	\$60 436	\$151 924
Cost per patient (No.)	\$126 (479)	\$177 (857)
Panel IgE		
Total cost	\$624 022	\$18 575
Cost per patient (No.)	\$402 (1551)	\$244 (76)
Total cost	\$684 458	\$170 499
Cost per patient (No.)	\$399 (1715)	\$192 (887)

\$192.22 for allergists; Table 4). The majority of this discrepancy was relevant to ordering sIgE panels, which cost on average \$402.34 per patient when ordered by PCPs compared with \$244.41 per patient when ordered by allergists.

DISCUSSION

To our knowledge, this is the first study to quantify and characterize the use of food allergen sIgE tests by PCPs. Our findings demonstrate significant discrepancies in the quantity and cost associated with ordering food allergen panels by PCPs compared with allergists. In addition, PCPs were more likely to order single-food sIgE tests for foods that are infrequent causes of allergy in children, such as strawberry, beef, and tomato. PCPs further removed from residency training ordered

more sIgE tests overall, especially panels, which suggests a possible lack of understanding or slow adoption of up-to-date food allergy clinical guidelines.⁶ Collectively, these findings reflect a need for additional education to ensure the most appropriate ordering and interpretation of sIgE tests for the evaluation of food allergy.

The discrepancy in use of sIgE panels was most apparent in orders for the Childhood Allergy Profile, which was only ordered 2 times during the study period by allergists, compared with 383 orders from PCPs. This profile contains 5 aeroallergens (cat, dog, dust mite, cockroach, and alternaria) that rarely cause clinical symptoms in infants <12 months of age who may be suspected of having food allergies. Understanding of the components of each panel as well as clinical relevance is important in

both ordering the proper test and interpretation of results.

The clinical history is the most important factor when determining whether a food allergy may be present.⁹ Historical elements of importance include the type of food reported to cause symptoms, timing of symptom onset, types of symptoms, and recurrence of symptoms with subsequent ingestion of the food in question.^{3,6} In children, egg, cow's milk, and peanut allergies are most common,^{2,14,15} whereas peanut, tree nuts, and seafood allergies are more common in adults.¹⁶ Knowledge of the important historical elements, spectrum of food-related adverse reactions, and common causes of IgE-mediated food allergy is important to determine which foods may warrant testing and also to avoid unnecessary testing.¹⁷⁻²²

In 2012, the American Board of Internal Medicine and American Academy of Allergy, Asthma and Immunology published their first *Choosing Wisely* series, which highlights 10 areas of unnecessary testing.²³ Number 7 on this list states: "Don't perform food IgE testing without a history consistent with potential IgE-mediated food allergy." There is also no indication to remove food from someone's diet based solely on a "positive" sIgE result. Many patients may be sensitized with a detectable sIgE to foods but not experience any reactions with exposure.¹¹ Both skin prick and serum-specific IgE testing for foods have high rates of falsely elevated results.²⁴ This can result in misinterpretation, improper diagnosis, and unnecessary dietary elimination. In addition, the 95% positive predictive values have only been established for egg, milk, and peanut.²⁵ Positive predictive values for other common allergenic foods, such as fish and tree nuts, are not as well established.⁵ Thus, interpretation of sIgE levels to any

other foods is based on clinical history and experience of the ordering physician.

In a recent study, Bird et al¹⁰ demonstrated the unnecessary clinical and economic burden associated with use and misinterpretation of food sIgE panels by PCPs. Among 797 children referred to their A/I practice over 18 months, 35% had previous food allergy panel testing. The authors determined the positive predictive value of panel testing for food allergy to be 2.2%. They also found that only 32.8% had a clinical history that warranted food allergy evaluation and there was an avoidable cost of ~\$79 000 associated with these evaluations.

We previously identified knowledge gaps surrounding food allergies among internal medicine and pediatric residents and attending physicians at 2 large academic medical centers.²⁶ In this study, 408 physicians answered a 9-question survey, including 6 questions related to food allergy diagnosis, testing, or management. Only 22% of respondents correctly answered a question regarding sIgE testing for food allergies and only 27% correctly identified the most common childhood food allergens. Overall, physicians with previous A/I elective experience or who recently completed residency training had the highest number of correct answers.

A survey published in 2007 identified significant differences in the understanding of prevalence, causes, and presentation of food allergies among nonallergists compared with allergists.²⁷ Nonallergists were more likely to misidentify common causes of food allergy, order nonvalidated diagnostic tests, and recommend broader elimination diets when compared with allergists.²⁸ A similar survey by Gupta et al²⁹ was published in 2010. In this survey of 407 pediatricians and family practitioners, 68% of

PCPs responded that a positive sIgE is sufficient to diagnose food allergy and only 28% felt comfortable interpreting laboratory tests to diagnose food allergy.²⁹

Lack of understanding of food allergies and testing by PCPs is multifactorial but likely related to demands on their time and challenges in keeping up with an ever-growing body of evolving scientific evidence and changing clinical guidelines. Limited access to board-certified A/I consultants for patient referrals or A/I training programs for residency elective rotations may contribute as well.

In our study, specialists in other fields, NPs, and PAs ordered 21.3% of all sIgE tests. Similar to PCPs, this group of clinicians collectively ordered food allergen panels (31.7%) more frequently than allergists. Given the widespread availability of sIgE testing, which can be ordered by any provider, educational efforts should not only be directed at PCPs, but other specialists and NP/PAs as well.

Strengths of our study include the large number of laboratory orders and physicians included in the database, details regarding types of food allergen sIgE orders placed, and inclusion of the duration of practice for each physician. Major limitations include an inability to assess the clinical history of any patients who had testing performed or the interpretation and management of the test results. In addition, the cost analysis does not take into account any other charges, such as office visits, follow-up skin prick testing, oral food challenges, or provision of epinephrine auto-injectors. However, given the findings from Bird et al,¹⁰ it is reasonable to extrapolate that the sheer volume of sIgE panels ordered by providers in our study would lead to considerable additional cost and likely unnecessary dietary elimination.

The availability of serum IgE testing for PCPs is extremely important for

their ability to evaluate patients with potential food allergy, particularly if access to allergists and/or skin prick testing is limited. However, to avoid unnecessary cost and potential misinterpretation, PCPs should refrain from ordering any sIgE panel tests containing foods, particularly if the clinical history is not suggestive for IgE-mediated food allergy. In support of this, the first recommendation from the *Choosing Wisely* list states: "Don't perform unproven diagnostic tests, such as immunoglobulin G testing or an indiscriminate battery of IgE tests, in the evaluation of allergy²³." Instead, PCPs should evaluate concern for food allergy by ordering individual sIgE tests only to foods for which there is a clinical history consistent with IgE-mediated food allergy. Ideally, commercial laboratories would consider removing sIgE panels containing foods from their available tests to prevent unnecessary cost expenditures.

Medical societies, clinical guidelines, and allergists can all serve as potential resources for educational efforts to help increase the knowledge and understanding of PCPs in regard to the ordering and interpretation of food sIgE testing. Future research should include confirmation of our findings in other geographic locations and patient populations as well as evaluation of trends over time. In addition, large scale studies with inclusion of clinical outcomes would offer broader insight into the potential impact from use of food allergy sIgE panels.

CONCLUSIONS

In this study, PCPs ordered the majority of commercially available food allergen IgE panels, which has been associated with overdiagnosis of food allergy, unnecessary dietary elimination, and increased cost.

Ideally, laboratories should limit food allergen panels from available testing options. In addition, both laboratories and allergists should educate health care providers regarding the ability to order single-food sIgE tests when clinically indicated. Dissemination of evidence-based clinical practice guidelines and ongoing research regarding the impact of food allergy IgE testing will ideally assist PCPs in the ordering and interpretation of these tests.

ABBREVIATIONS

A/I: allergy and immunology
GI: gastroenterology
IgE: immunoglobulin E
NCH: Nationwide Children's Hospital
NP: nurse practitioner
PA: physician assistant
PCP: primary care provider
sIgE: specific immunoglobulin E

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